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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,488	10/29/2003	Bernard Cuenoud	4-20890C	7737

1095 7590 06/13/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,488	CUENOUD ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

It appears that the wording of Claims 42-47 and 51 in the instant application fail to follow the standards or format for U.S. applications, such as "A method for", instead of "Use of". It is suggested that the claim language be corrected so as to place the application in better form for examination.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-58, drawn to an oligonucleotide derivative containing a nucleoside building block compound comprising the Formula I, classified in class 536, subclass 24.5.

2. **Should Applicant elect Invention I, a further group restriction is required under 35 U.S.C. 121.** Claims 1 and 24 contain improper Markush Groups that are not compliant with *In re Harnisch* and thus form paragraph *M.P.E.P. 8.01 Election of Species* does not apply. Applicant is required to elect a single disclosed molecular composition of the radical "A" recited specifically in Claim(s) 1, 2, 10, 24, 25, and 33 for prosecution on the merits to which the claims shall be restricted. Therefore, election is required of one of Inventions I-II, inventive groups (a)-(c) below (see Claim 1 for example), wherein in "A" is a radical, specifically:

   a) $-C(H)(R_3)-N(R_1)(R_2)$,

   b) a radical of formula (IVa), or

   c) a radical of formula (IVb).

Claims 1 and 24 link the Invention I, inventive groups (a)-(c).

Inventions I, inventive groups (a)-(c) are distinct because,

Inventions I, inventive groups (a)-(c) are unrelated. The (A) radicals are distinctly different in structure, as illustrated by the numerous variations of heteroatoms, linear and branched carbon chains, and monocyclic heteroatom groups. Furthermore, these unrelated structures are not obvious variations of each other because one skilled in the art does not expect aromatic ring systems to have the same chemical properties as non-aromatic ring systems, such as affecting bioavailability, toxicity or bioactivity of the compound. A reference rendering a compound of group (c) as anticipated or obvious over the prior art would not necessarily also render the compound of formula IVb as anticipated or obvious over the prior art.

Because these inventions are distinct for reasons given above, and because a search of one radical formula structure does not necessarily overlap with that of another radical formula structure, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed molecular composition of the radical "A", even though this requirement is traversed. Failure to elect a molecular composition of the radical "A" consonant with Applicant's elected Invention, may result in a notice of non-responsive amendment.

3. **Should Applicant elect Invention I and any of Invention I, inventive groups (a)-(c) from above, a species election is required under 35 USC 121.** Currently, Claims 1, 10, 24, 25, 33, 40 and 56 of this application are directed to a plurality of disclosed, patentably distinct radical species that prohibit proper examination of these claims. Therefore, for each symbolic radical below (i-xiii), election is required under 35 U.S.C. 121 of:

i) one (R_1) and (R_2) radical from the list consisting of the radicals recited in Claims 1-7 and 24-30,

ii) one (R_3) radical from the list consisting of the radicals recited in Claims 1, 8, 10, 24, 31 and 33,

iii) one (R_4) radical and from the list consisting of the radicals recited in Claims 1, 8, 24, 31 and 40,

iv) one (R_5) and (R_6) radical from the list consisting of the (R_5) radicals recited in Claims 1-3 and 24-26,

v) one (R) radical of Formula IVa from the list consisting of the radicals recited in Claims 1 and 24,

vi) one (R) radical of Formula IVb from the list consisting of the radicals recited in Claims 1 and 24,

vii) one (X) radical of Formula II from the list consisting of the (X) radicals recited in Claims 1 and 24-26,

viii) one (X) radical of Formula B and one (X) radical of Formula C from the list consisting of the (X) radicals recited in Claim 40,

ix) one (Y) radical of Formula III from the list consisting of the (Y) radicals recited in Claims 1 and 24,

x) wherein the (V) radical is the species of an internucleosidic bridging moiety and one (V) radical is a moiety from the list consisting of the bridging groups recited in Claim 15-18 or the (V) radical is the species of a terminal radical moiety and one (V) terminal radical is a moiety from the list consisting of the terminal radicals recited in Claim 19-20,

xi) wherein the (W) radical is the species of an internucleosidic bridging moiety and one (W) radical is a moiety from the list consisting of the bridging groups recited in Claim 15-18 or the (W) radical is the species of a terminal radical moiety and one (W) terminal radical is a moiety from the list consisting of the terminal radicals recited in Claim 19-20,

xii) one (R_8) radical from the respective list consisting of the (R_8) radicals recited in Claim 15, and

xiii) one (Va) and (Wa) trityl-type protecting group from the list consisting of the protecting groups recited in Claim 39.

Therefore, election is required under 35 U.S.C. 121 of one species type from the respective lists (i-xvii) above consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The numerous variations in the number, position and type of heteroatoms, ring structures, and linear or branched carbon chains result in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect aromatic ring systems to have the same chemical properties as non-aromatic ring systems. Each of the radical species moieties confers a unique, non-obvious property onto the modified nucleoside derivative that will directly impact the bioavailability, toxicity or bioactivity of the compound. Given the breadth of the claimed, unrelated structures, a search for all possible species at each of the recited radical groups imposes an exceptional burden on the Office. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Failure to elect species consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant elect Invention I and any of Invention I, inventive groups (a)-(c) and any symbolic radical moiety species from (i)-(xiii) above, a further species restriction is required under 35 U.S.C. 121. Claims 1, 24, 40 and 56 are generic to a plurality of disclosed patentably distinct (B) and (B') radical core structures that prohibit proper examination of these claims. Therefore, election is required under 35 U.S.C. 121 of one (B) and (B') radical structure from the list consisting of the radicals recited in Claims 11-14 and 34-36 consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

While the core structure of the (B) and (B') compounds are all heterocycles, they are distinctly different, as illustrated by the mono-cyclic and bi-cyclic structures, as well as the variable number and position of heteroatoms, such as Nitrogen, contained in each ring. Furthermore, the variation of claimed, possible heteroatoms and rings confer unique, non-obvious properties on the (B) and (B') radicals, such as affecting bioavailability, toxicity or bioactivity of the compound. A reference rendering a compound of formula V1 as anticipated or obvious over the prior art would not necessarily also render the compound of formula V10 as anticipated or obvious over the prior art. Because these inventions are inherently distinct for reasons given above, and because a search of a mono-cyclic heterocycle does not necessarily overlap with that of a bi-cyclic heterocycle, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed (B) or (B') radical for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Failure to elect (B) or (B') radical consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant elect Invention I and any of Invention I, inventive groups (a)-(c) and any symbolic radical moiety species from (i)-(xiii) and any (B) or (B') radical moiety species from above, a further species election is required under 35 USC 121. Currently, Claims 1, 10, 24, 25, 33, 40 and 56 of this application are directed to a plurality of disclosed, patentably distinct radical species that prohibit proper examination of these claims. Therefore, for each symbolic radical below (xiv-xv), election is required under 35 U.S.C. 121 of:

xiv) one (R_{b1}), (R_{b2}), (R_{b3}), (R_{b4}) and (R_{b5}) radical from the respective list consisting of the radicals recited in Claims 11-13, 34-35, and

xv) one (B') protecting group from the list consisting of the protecting groups recited in Claim 37.

Therefore, election is required under 35 U.S.C. 121 of one species type from the respective lists (xiv-xv) above consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The numerous variations in the number, position and type of heteroatoms, ring structures, and linear or branched carbon chains result in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect aromatic ring systems to have the same chemical properties as non-aromatic ring systems. Each of the radical species moieties confers a unique, non-obvious property onto the modified nucleoside derivative that will directly impact the bioavailability, toxicity or bioactivity of the compound. Given the breadth of the claimed, unrelated structures, a search for all possible species at each of the recited radical groups imposes an exceptional burden on the Office. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the

examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Failure to elect species consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER